

REMARKS

Claims 1, 9-10, 12-13, and 15-25 are pending. Claims 2-8, 11, and 14 are canceled. Applicants reserve the right to pursue the subject matter of any canceled claims in one or more continuing applications. The listing of claims appears in this paper for convenience. No amendments are made in this paper. No new matter is entered.

Response to Election of Species Requirement

In response to the Restriction Requirement of June 2, 2009 requiring restriction between Group I (claims 1, 9-10, 12-13, and 15-23) and Group II (claims 24-25), Applicants elect Group I (claims 1, 9-10, 12-13, and 15-23, drawn to compounds/compositions), with traverse. The traversal is on the basis that the claims define a special technical feature over the art cited by the Office Action, and there is no burden on the examiner to the search of the entire scope of the claims.

The Office Action argues that the English translation of Chapter 3 of the Ph.D. thesis of Angel Lopez Macia teaches kahalalide F compounds “in which L-Orn8 has a protecting group (i.e. Boc)” and that “[s]ince all of the other positions of the compound (i.e. positions 1-7, 9-14) are the known components of kahalalide F the technical features are not a contribution over the prior art and the claims lack unity” (Office Action, p. 3).

Contrary to the assertion by the Office Action, section 3.2.2.2 of the Angel Lopez Macia Thesis relates to an attempt to synthesize the peptidyl-resin compound 5-McHex-Val-Thr(tBu)-Val-Val-Pro-Orn(Boc)-Ile-Thr(Val-Fmoc)-Ile-Val-ClTrt-PS. The named compound is a chloro trityl resin linked to units of 5-McHex-Val-Thr(tBu)-Val-Val-Pro-Orn(Boc)-Ile-Thr(Val-Fmoc)-Ile-Val-. This compound is a synthetic compound that differs from the claimed compounds of this invention in at least the following ways:

- 1) Link to a polymeric resin. The presently claimed compounds are not linked to a polymeric resin.
- 2) Lack of certain amino acids that are required in the presently claimed compounds. The compound of section 3.2.2.2 lacks the Phe amino acid and the (Z)-Dhb moiety (i.e. positions 2 and 3) from the kahalalide F core structure.
- 3) Lack of the kahalalide F ring system. The compound of section 3.2.2.2 lacks the kahalalide F ring system, and lacks the requisite amino acids to even form the ring system.
- 4) Modification of multiple amino acid components. The compound of section 3.2.2.2 has modifications at three different amino acids- Thr, Orn, and Val are modified with tBu, BOC, and FMOC groups, respectively.

Moreover, the final paragraph of section 3.2.2.2 teaches away from the use of the described compound, as the described compound has too many “impediments” which preclude its use (see English translation, final paragraph of section 3.2.2.2).

In an effort to advance prosecution such that a third Restriction is avoided, Applicants further note that the compounds described in the Angel Lopez Macia Thesis have modifications on at least two exocyclic amino acids, i.e., at least on the Thr amino acid at position 12 and the Orn amino acid at position 8 (see, for example, Chapter 3, figure 3.18 and Chapter 4, figure 4.9). As such, the compounds disclosed by the Angel Lopez Macia Thesis do not fall within the scope of the instant claims, and therefore the instant claims define a special technical feature, and the lack of unity holding must be withdrawn.

In summary, there is no disclosure in the Thesis of a kahalalide F analogue as claimed, wherein only the ornithine amino acid at position 8 is substituted by another natural or non natural amino acid, and/or is masked with one or more substituent organic groups, and wherein said compound may optionally differ from formula 1 by modification of the terminal acyl group.

In addition, there is no serious burden to the Examiner in searching both Groups I and II because the Groups overlap in the subject matter of the compounds/compositions, i.e. the methods of Group II incorporate all of the elements of Group I. According to the MPEP,

If the search and examination of all the claims in an application can be made without serious burden, the examiner must examine them on the merits, even though they include claims to independent or distinct inventions.

See MPEP 803. Even assuming that the Groups lack unity of invention, Applicants believe that the Examiner must examine them on the merits because examination can be made without serious burden, as directed by the MPEP. In the event that the Examiner maintains the Restriction Requirement, Applicants understand that upon determination of allowable subject matter, any claims from Group II that include all the elements of Group I will be eligible for rejoinder.

In response to the Election of Species Requirement, Applicants elect [Ne(Me)₃-Lys⁸, (4S)-MeHex¹⁴]-KF, which is compound 93, disclosed in Example 10, with traverse. The compound can also be found in Table VIII of the specification. The claims readable on the elected species are claims 1, 10, 12-13, 15, 17-18, 20-21, and 23-25. Applicants understand that upon allowance of a generic claim, Applicants will be entitled to consideration of additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim.

Applicants traverse the Election of Species Requirement on the basis that the pending claims share a special technical feature which is the modification in the identity of the L-Orn amino acid at position 8. The modification of Orn-8 leads to substitution with another natural or non-natural amino acid, and/or masking with one or more substituent organic groups. The

reference cited by the Examiner (Angel Lopez Macia Thesis) does not destroy the special technical feature of the pending claims, as discussed above.

Applicants also traverse the Election of Species Requirement on the basis that Applicants are entitled to examination of a reasonable number of species (*i.e.*, reasonable being more than 1). Furthermore, there is no serious burden to the Examiner in searching the generic claims because USPTO examination of chemical compounds routinely covers large numbers of compounds, and USPTO examiners are accustomed to such examination. According to the MPEP,

If the search and examination of all the claims in an application can be made without serious burden, the examiner must examine them on the merits, even though they include claims to independent or distinct inventions.

See MPEP 803. Even assuming that the various species lack unity of invention, Applicants believe that the Examiner must examine them on the merits because examination can be made without serious burden, as directed by the MPEP.

AUTHORIZATION

The Commissioner is hereby authorized to charge any fees which may be required for consideration of this paper to Deposit Account No. **50-3732**, Order No. 13566.105010. In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. **50-3732**, Order No. 13566.105010.

Respectfully submitted,
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Dated: June 19, 2009

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